JUN 2 0 2014

K140155

1500 Waukegan Road
Waukegan, IL 60085

www.cardinalhealth.com

**510(k) SUMMARY**
Secure-Gard® Surgical and Procedure Masks

| | |
|---|---|
| Manufacturer: | Cardinal Health 200, LLC<br>1500 Waukegan Road<br>Waukegan, IL 60085 |
| Regulatory Affairs Contact: | Lavenia Ford<br>1500 Waukegan Road<br>Waukegan, IL 60085 |
| Telephone Number: | (847) 887-3323 |
| Fax Number: | (847) 887-2461 |
| Date summary Prepared: | May 21, 2014 |
| Trade Name: | Secure-Gard® Surgical Mask<br>Secure-Gard® Procedure Mask |
| Regulation Number/Device Class: | Class II per 21 CFR § 878.4040 |
| Regulation Name: | Surgical Apparel |
| Common Name: | Surgical Mask<br>Procedure Mask |
| Product Code: | FXX |
| Predicate Device: | K111402 –Kimberly-Clark, KC300 Face Mask(s) |

**Description**

The Cardinal Health Secure-Gard® surgical and procedure masks are identified by Regulation 21 CFR 878.4040 with product code FXX.

The Cardinal Health Secure-Gard® surgical and procedure masks are all the same four-layer masks constructed of 1 layer of nonwoven cellulose (inner facing), 1 layer of nonwoven polyolefin melt blown (media), 1 layer of nonwoven polyester/polyethylene blends (media), and 1 layer polyolefin spunbond material (outer facing). The four layers of the mask body are collated and sonically welded around the edges to enclose the filter media. The mask is provided with nonwoven polyolefin ties or polyester-spandex earloops (both attached by ultrasonic welding). A malleable nosepiece is placed within the binding for comfort and individualized fit around the wearer's nose. The surgical masks will be provided with or without an eye shield. Cardinal Health surgical and procedure masks are a single use, disposable device provided non-sterile

**Indications for Use**

Cardinal Health Secure-Gard® surgical and procedure masks are intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health Secure-Gard® surgical and procedure masks are single use, disposable devices provided non-sterile.

This submission covers 7 catalog numbers of Secure-Gard® surgical and procedure masks models, see **Table 1** below. Each model is the same four-layer mask constructed of 1 layer of nonwoven cellulose (inner facing), 1 layer of nonwoven polyolefin melt blown (media), 1 layer of nonwoven polyester/polyethylene blends (media), and 1 layer polyolefin spunbond material (outer facing) and has been tested according to ASTM 2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks.

**Table 1: Product Description and Catalog Number**

| Catalog # | Trade Name | Design Features | Color |
|---|---|---|---|
| AT74535 | Secure-Gard® surgical mask | Anti-fog foam strip and ties | Teal and Purple |
| AT74635 | Secure-Gard® surgical mask | Anti-fog foam strip, eye shield, and ties | Teal and Purple |
| AT74635-I | Secure-Gard® surgical mask | Anti-fog foam strip, anti-glare eye shield, and ties | Teal and Purple |
| AT744235 | Secure-Gard® surgical mask | Light weight anti-fog strip and ties | Teal and Purple |
| AT744335 | Secure-Gard® surgical mask | Light weight anti-fog strip with eye shield and ties | Teal and Purple |
| AT74531 | Secure-Gard® procedure mask | Earloops | Teal and Purple |
| AT74631 | Secure-Gard® procedure mask | Eye shield and earloops | Teal and Purple |

**Device and Predicate Device Technical Characteristics**

The Cardinal Health Secure-Gard® surgical and procedure face masks are substantially equivalent to the predicate device Kimberly-Clark KC300 of K111402 in intended use and principles of operation see **Table 3** below. The Cardinal Health Secure-Gard® surgical and procedure masks and predicate masks meet ASTM F2100-11 as shown below in **Table 11**.

**Table 3: Comparison of Predicate device and Cardinal Health Secure-Gard® Surgical and Procedure masks**

| Element of Comparison | Kimberly-Clark (KC300) | Cardinal Health Secure-Gard® Surgical and Procedure Masks |
|---|---|---|
| **Intended Use** | The Kimberly Clark KC300 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The Kimberly Clark KC300 face mask(s) is a single use, disposable device(s), provided non-sterile. | **Secure-Gard Surgical Mask** Cardinal Health Secure-Gard® surgical masks are intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health Secure-Gard® surgical masks are single use, disposable devices provided non-sterile<br><br>**Secure-Gard Procedure Mask** Cardinal Health Secure-Gard® procedure masks are intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health Secure-Gard® procedure masks are single use, disposable devices provided non-sterile |
| **Material Composition** | 4 layer mask made from nonwoven polyester blends and polypropylene materials | **Secure-Gard Surgical Mask** 4 layer mask made from 1 layer of nonwoven cellulose (inner facing), 1 layer of nonwoven polyolefin melt blown (media), 1 layer of nonwoven polyester/polyethylene blends (media), and 1 layer polyolefin spunbond material (outer facing)<br><br>**Secure-Gard Procedure Mask** 4 layer mask made from 1 layer of nonwoven cellulose (inner facing), 1 layer of nonwoven polyolefin melt blown (media), 1 |

| | | |
|---|---|---|
| | | layer of nonwoven polyester/polyethylene blends (media), and 1 layer polyolefin spunbond material (outer facing) |
| **Specifications and Dimensions** | **KC300 Surgical Mask**<br>7.0"x3.7"<br><br>**KC300 Procedure Mask**<br>6.9"x3.8" | **Secure-Gard Surgical Mask**<br>AT74535 – 7"x4"<br>AT74635 – 7 ¼"x4 1/8"<br>AT74635-I – 7 ¼"x4 1/8"<br>AT744235 – 7"x4"<br>AT744335 – 7"x4"<br><br>**Secure-Gard Procedure Mask**<br>AT74531 – 7"x3 3/8"<br>AT74631 – 7"x3 3/8"<br><br>See **Appendix I** for mask specifications |
| **Mask Style** | Pleated | **Secure-Gard Surgical Mask**<br>Pleated<br><br>**Secure-Gard Procedure Mask**<br>Pleated |
| **Design Features** | **KC300 Surgical Mask**<br>Fluidshield Fog-Free<br><br>**KC300 Procedure Mask**<br>Fluidshield Fog-Free | **Secure-Gard Surgical Mask**<br>AT74535 – Anti-fog foam strip and Ties<br>AT74635 – Anti-fog foam strip, Eye shield, and Ties<br>AT74635-I – Anti-fog foam strip, Anti-glare eye shield, and Ties<br>AT744235 – Lightweight anti-fog strip and Ties<br>AT744335 – Lightweight anti-fog strip, Eye shield, and Ties<br><br>**Secure-Gard Procedure Mask**<br>AT74531 – Earloops<br>AT74631 – Eye shield and Earloops |
| **Physical Testing** | Predicate device was tested according to ASTM F2100-11 Level 3 in previous 510(k) submission K111402. | **Secure-Gard Surgical Mask**<br>Device was tested in accordance with ASTM F2100-11, and meets Level 3 requirements<br><br>**Secure-Gard Procedure Mask**<br>Device was tested in accordance with ASTM F2100-11, and meets Level 3 requirements<br><br>See **Appendix G** for all test data |
| **Biocompatibility** | Predicate device was tested according ISO 10993 | **Secure-Gard Surgical Mask**<br>Device was tested in accordance to ISO 10993 and passed |

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| | | acceptance criteria<br><br>**Secure-Gard Procedure Mask** Device was tested in accordance to ISO 10993 and passed acceptance criteria<br><br>**Appendix H** for all test data |

**Summary of Testing**

The Cardinal Health Secure-Gard® surgical and procedure masks have been tested according to ASTM 2100-11 and standards which comprise ASTM F2100-11, Standard Specification for Performance of Materials Used in Medical Face Masks, see **Table 11** below.

**Table 11: Summary of ASTM F2100-11 Testing – Cardinal Health Secure-Gard® Surgical and Procedure Masks compared to Predicate**

| Test | Acceptance Criteria per ASTM F2100-11 Level 3 (AQL = 4.0%) | Predicate device test results K111402 (KC300) | Current device test results | |
|---|---|---|---|---|
| | | | ASTM F2100-11 Level 3 | Average |
| ASTM F1862 Synthetic Blood | 160 mmHg | Pass | 32/32 Pass | Not Applicable |
| ASTM F2101 BFE | ≥ 98% | Pass | 32/32 Pass | 99.4 - 99.7% |
| ASTM F2299 PFE at 0.1 micron | ≥ 98% | Pass | 32/32 Pass | 98.6 - 99.1% |
| Mil-M-36954C Delta P | < 5.0 $mmH_20/cm^2$ | Pass | 32/32 Pass | 3.1– 3.5 $mmH_20/cm^2$ |
| CPSC 1610 Flammability | Class 1 | Pass | 32/32 Pass Class 1 | Not Applicable |

All results of testing met ASTM F2100-11 Level 3 acceptance criteria. ASTM F2100-11 Level 3 was performed at an AQL of 4% (32 samples tested, accept on 3 failures and reject on 4 failures).

**Summary of Testing**

Based on the results of the biocompatibility and physical performance testing the Secure-Gard® surgical and procedure masks are as safe and as effective for their intended use as the predicate. The Secure-Gard® surgical and procedure masks are substantially equivalent to the predicate device, in terms of general intended use performance testing, material composition, configurations/dimensions, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-000

June 20, 2014

Cardinal Health 200, LLC
Ms. Lavenia Ford
Manager, Regulatory Affairs
1430 Waukegan Road
Waukegan, Illinois 60085

Re: K140155
Trade/Device Name: Secure-Gard® Surgical and Procedure Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask
Regulatory Class: Class II
Product Code: FXX
Dated: May 21, 2014
Received: May 22, 2014

Dear Ms. Ford,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140155

Device Name
Secure-Gard® surgical and procedure masks

Indications for Use *(Describe)*

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| AT74631 | Secure-Gard® procedure mask | Eye shield and earloops | Teal and Purple |

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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